

Claim Amendments.

Claims 6 and 8 have been amended as described in (1) below.

1. CLAIM REJECTIONS: 35 U.S.C. § 112 first paragraph.

Claims 6-9 stand rejected as allegedly containing added matter, due to the phrase ‘non-radioactive organic ligand’ occurring in independent claims 6 and 8. Dependant claims 7 and 9 respectively are also affected.

Applicants have amended independent claims 6 and 8 to restore the previous acceptable claim language (‘organic ligand’). The objection should therefore be withdrawn and claims 6-9 allowed.

2. CLAIM REJECTIONS: 35 U.S.C. § 103(a).

New grounds of rejection are raised, wherein claims 1-14 stand rejected as lacking an inventive step over Rajopadhye (US 5,888,970) in view of Yamaguchi (JP 11-99191) in further view of either Schott Glaswerke (DE 29,609,958 U1) or Walther (US 6,200,658).

The Examiner suggests that it would have been obvious to modify Rajagopadhye using Yamaguchi, Schott Glaswerke and Walther to coat the inner surface of a radiopharmaceutical container with silica.

The Examiner argues (Page 6 as well as reason #3 on page 8 of the current Office Action) that the motivation to combine Rajopadhye and Yamaguchi stems from the advantages taught by Yamaguchi to:

“...prevent highly adsorbable radiopharmaceuticals from being adsorbed thereon and provide a clear description of the vial contents and amounts thereof...”.

Applicants firstly point out that, if the Examiner’s logic is followed that would inevitably provide containers having reversed lettering on the outer surface. Thus, applicants reiterate their previous argument, that Yamaguchi makes clear therein at e.g. [0005], [0010], [0011] and [0016]-[0019] that the advantages of description of contents etc. are provided by reversed text lettering on the outside of the vial (not the silica coating). That feature is completely different to the silica coating on the inside of the vial. Since the Examiner contends that the person skilled in the art would be motivated to use such advantages of Yamaguchi, the combination [Rajopadhye and Yamaguchi] leads to subject matter outside the scope of the present claims – since the combination would lead to radiopharmaceutical vials having the reversed lettering of Yamaguchi, not the silica coating.

The Examiner is invited to provide a detailed page/line citation of Yamaguchi where the silica coating provides the description of the vial contents.

The Examiner also argues that Yamaguchi teaches "...containers for pharmaceuticals which can prevent highly adsorbable radiopharmaceuticals from being adsorbed thereon...."

Applicants secondly point out that Yamaguchi teaches [at 0008] refers to the invention therein being useful for "highly adsorbable radiopharmaceuticals". Thus, the clear teaching of Yamaguchi itself is that the invention therein is useful for highly adsorbable radiopharmaceuticals. Rajopadhye does not, in fact, disclose, teach, or suggest the radiopharmaceuticals disclosed therein suffering from any adsorption problems. The only logical conclusion is that the radiopharmaceuticals therein are not highly adsorbable radiopharmaceuticals. The person skilled in the art could therefore have no motivation to combine Rajopadhye and Yamaguchi as suggested by the Examiner, since the radiopharmaceuticals of Rajopadhye do not fit the criterion taught to be necessary by Yamaguchi.

Applicants stress that the above logic is based on Yamaguchi itself. The Examiner's argument involves attributing a teaching to Yamaguchi that contradicts the document itself, that the invention is useful for all radiopharmaceuticals. Applicants contend that the teaching of Yamaguchi itself to the person skilled in the art must be followed.

The combination Rajopadhye and Yamaguchi is therefore believed invalid, and for all the above reasons and the rejection of claims 1-14 should be withdrawn.

The Examiner also argues (page 8 reason #2 of the current Office Action) that the motivation to combine Rajopadhye and Schott Glaswerke stems from the advantages taught by Schott Glaswerke “for radiopharmaceuticals.” The Examiner also argued that the disclosure of Schott Glaswerke is in the field of radiopharmaceuticals (page 9 last paragraph of the current Office Action), and that hence it is properly combinable with Rajopadhye.

Applicants respectfully refer to their previous request (which the Examiner has not responded to): that the Examiner is requested to cite specifically where in Schott Glaswerke any reference to radioisotopes and/or radiopharmaceuticals can be found to justify such an assertion. The Examiner’s detailed description of Schott Glaswerke (bridging pages 7 and 8 of the current Office Action) is silent on radiopharmaceuticals, so is at variance with the conclusions drawn.

Applicants can find reference only to “...the storage of pharmaceutical or diagnostic solutions” and “blood or blood samples”. Schott Glaswerke read without hindsight is silent on radioisotopes and formulations thereof used in medicine, i.e. radiopharmaceuticals.

Applicants respectfully point out that whether or not Schott Glaswerke discloses radiopharmaceuticals is a matter of fact which is crucial to the examination of the present application. The Examiner is therefore (again) asked to provide detailed page and line citations in the document itself, where the cited disclosure can be found. If such detailed citations are not forthcoming, then Applicant's position is that the Examiner has misconstrued Schott Glaswerke and the objections based on that construction of the reference must be withdrawn.

Rajopadhye and Schott Glaswerke are not believed to be properly combinable, since they are clearly in very different fields of endeavor. Evidence for that interpretation can be found in Walther (US 6,200,658) which the Examiner relies on as an alternative to Schott Glaswerke. Comparison of the US Classification codes for Rajopadhye and Walther shows no subject codes in common and the rejection of claims 1-14 should be withdrawn.

Conclusion

In view of the remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and objections, and allowance of the current application are respectfully requested.

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Furthermore, the Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Respectfully submitted,

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